



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 2 2004

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Frederick S. Mayer, R.Ph., M.P.H.
Pharmacists Planning Service, Inc. (PPSI)
101 Lucas Valley Road, Suite 210
San Rafael, CA 94903

Re: Docket No. 2003P-0196/CP1

Dear Mr. Mayer:

This letter responds to your citizen petition dated April 9, 2003, requesting that the Food and Drug Administration (FDA) switch Nicotrol Inhaler (Nicotine Inhalation System) from prescription-only to over-the-counter (OTC) status. You amended your petition on April 28, 2003, to request that Nicotrol Inhaler be sold OTC "ONLY UNDER A PHARMACIST'S SUPERVISION as a third class of drugs" (emphasis in original).

You describe the "third class of drugs category" to include "injectable needles, syringes, insulin, pseudoephedrine, ephedrine products, etc." You ask FDA to add the Nicotrol Inhaler to this category, to be dispensed or sold in conjunction with counseling and supervision by a pharmacist or healthcare provider, including a warning that it not be sold to minors.

For the reasons set forth below, we deny your petition.

FDA's authority to classify a drug as prescription-only or OTC and its ability to remove a drug from the prescription category and designate it as OTC are set forth in section 503(b) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 353(b), which states:

(1) A drug intended for use by man which —

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug; shall be dispensed only [upon prescription]. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

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(3) The Secretary may by regulation remove drugs subject to section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

The regulation implementing the authority set forth in section 503(b)(3) is codified in § 310.200 (21 CFR 310.200).

Section 310.200 requires that the Commissioner make a two-fold finding before switching a drug product with an approved new drug application (NDA) from prescription to OTC status. First, the Commissioner must find that "the prescription-dispensing requirements are not necessary for the protection of the public health by reason of the drug's toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use." Second, the Commissioner must find that the drug is "safe and effective for use in self-medication." It is our conclusion that the information before us at this time provides an inadequate basis upon which to switch the Nicotrol Inhaler to OTC status (available only under a pharmacist's supervision) under § 310.200.

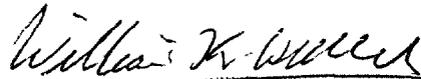
You cite a number of facts that you claim support a switch, including the large number of smokers in the United States, the belief that no new products have been produced in recent years, and the belief that the inhalation device is uniquely designed to address the smoking ritual and oral fixation. We agree that there are millions of smokers in the United States and it is desirable to expand the treatment armamentarium. We disagree that there have been no new products produced in recent years. In fact, a new nicotine replacement product, Commit Lozenge (nicotine polacrilex lozenge), was approved for OTC marketing on October 31, 2002. While the need for additional medications to treat tobacco dependence is not in dispute, there are products in development to address this need.

You recognize, as does the Agency, that the Nicotrol Inhaler is unique among currently marketed products in being an inhaler device for delivery of drug to the buccal mucosa. It is precisely because the inhaler device is unique in its delivery of drug that FDA must have adequate data that the prescription-dispensing requirements "are not necessary for the protection of the public health" and "that the drug is safe and effective for use in self-medication" under § 310.200, with or without counseling and supervision by a pharmacist or healthcare provider. FDA does not have sufficient data specific to the Nicotrol Inhaler to make these determinations at this time.

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Therefore, your petition requesting the Nicotine Inhaler be switched from prescription-only to OTC status, to be sold under pharmacists' supervision "behind-the-counter," is denied.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "William K. Hubbard".

William K. Hubbard
Associate Commissioner
for Policy and Planning